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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|------------------------------|------------------|
| 09/812,235 | 03/19/2001 | William S. Hurst | CRTS-5681 (1417A P 574)/1 | 9437 |
| 7590 | 06/30/2004 | | EXAMINER | CHAN, KO HUNG |
| Joseph B. Barrett, Esq. BAXTER HEALTHCARE CORPORATION Corporate Research & Technical Services One Baxter Parkway, DF3-3E Deerfield, IL 60015 | | | ART UNIT | PAPER NUMBER |
| | | | 3632 | |
| DATE MAILED: 06/30/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/812,235 | HURST ET AL. | |
| | Examiner | Art Unit | |
| | Korie H. Chan | 3632 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 April 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 12 and 18-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 12 and 18-48 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 27 April 2004 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Drawings

The proposed drawings correction filed 4/27/2004 are disapproved by the examiner because new figure 13a shows the pulley 182 in contact and at the edge of the box which would prevent its function. Examiner suggest drawing a line to pulley 182 then label and describe that line as "a suitable support for the pulley 182" in the specification. Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

Claim 34 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The entire limitation in claim 34, which depends from claim 29, has been recited in claim 29.

Claim Rejections - 35 USC § 112

Claims 12, 18-28, 36-38, 41, and 46-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 12, 36, and 37 are vague and indefinite for the reason that it is not clear whether or not applicant is claiming the hanger system in combination with the box and flexible container as the preamble sets forth an intended use but the body sets forth a positive connection as if in combination. Examiner has treated claims 12, 36, 37 as hanger system in combination with the hanger, flexible container, and box. Claim 18 is vague and indefinite. Claim 18 merely claims "a system" but does not recite what the system comprises but rather what the system is intended to be used in (e.g. for supporting 3-D flexible container within a box). It is not clear what the system encompasses. Claim 18 has been treated as claiming a hanger system intended for use with flexible container and a box. Claim 38,

lines 4-5, “having a **size** greater than the interior volume of the box” is vague as it not clear what size applicant is referring to. Examiner suggest “having a **volume** greater than the interior volume of the box”.

Claim Rejections - 35 USC § 102

Claims 12, 18-20, 22, 24-30, 32, 34, 37, 39, 41-44, 46, and 47, as best understood are rejected under 35 U.S.C. 102(b) as being anticipated by Haas et al (US patent no. 4,527,716). Haas discloses a hanger system for supporting a large volume flexible container forming a barrier to an interior of the container. the flexible container (13) disposed in a rigid box (12), the large-volume flexible container having sidewalls in supportive contact with sidewalls of the rigid box (26, figure 2) the system comprising a means (50, 51, 52, 60, 56) for upwardly biasing a top portion of the flexible container, the means being connected to the rigid box and the top portion of the flexible container, wherein the means further comprises a counter-weight or counter-force (55 and 56) is connected to the top portion of the flexible container (52, 60, 58) wherein the flexible container having a first perimeter defined by a substantially horizontal cross-sectional plane and the box having a second perimeter defined by the substantially horizontal cross-sectional plane when the flexible container is positioned within the box, the first perimeter being greater than the second perimeter (figure 2); wherein the top side of the flexible container with plurality of connection locations (44, 46) connected to the container hanger (50, 51); wherein at least one of the hanger (52) connect to a top side of the container spaced inward from the top outer perimeter edges; wherein the hanger

applies variable upward force (col. 4, lines 20-24) such that the hanger to flexible container connection is vertically movable during use.

Regarding the recitations in independent claim 18 and the claims that dependent therefrom such as claims 19, 24-28, and 41, applicant's intended use for supporting a flexible bag in a box with the various features of the bag and box is not accorded with patentable weight. Haas' does disclose a hanger system which is capable of being used with the claimed flexible bag and box.

A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claim 40 is rejected under 35 U.S.C. 102(b) as being anticipated by Rings et al (US patent no. 5,382,117). Rings discloses a large-volume flexible container support system, comprising : a box (2) having an interior volume, a large-volume flexible container inside of the box (2) and having a size greater than the interior volume of the box, the container forming a sterile barrier to an interior of the container, and a container hanger (9 and 10) connected to a top portion of the large-volume flexible container and biasing the top portion of the large-volume flexible container upward, wherein the

container hanger further comprises an elastic member assembly (9) connected to the top portion of the large-volume flexible container.

Claims 12 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Love (US patent no. 4,306,668). Love discloses a hanger system for supporting a large volume flexible container in a box, the large volume flexible container defining a sterile barrier to an interior of the container having a top side having a top outer perimeter edge and sidewalls in supportive contact with sidewalls (14, 15) of the box, the system comprising a container hanger (16, 17, figure 5) connected to the box and to a portion of the top side of the flexible container spaced inward from the top outer perimeter edge (figure 5) and applying an upward force to the portion of the flexible container wherein the flexible container has a perimeter greater than the perimeter of the box in the unstretched condition of the box along the same plane.

Applicant's intended for a box of rigid type in claim 12 is not accorded with patentable weight. Love's support system is capable of being used in a box of rigid type.

Claim Rejections - 35 USC § 103

Claims 35, 45, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Haas et al (US patent no. 4,527,716). Haas disclosed all the claimed features of applicant's invention except for perimeter of the flexible container is greater than the perimeter of the box in the range of 2%-10% nor the volume of the flexible container is at least 200 liters. It would have been an obvious matter of design choice to have the perimeter of the flexible container is greater than the perimeter of the

box in the range of 2%-10% and to have flexible container of at least 200 liters since applicant has not disclose any criticality or advantage in having such size or volume. Moreover other range of perimeter and volume would appear to perform as well.

Claims 12, 20, 21, 23, 29-31, 33, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Sasaki et al (US patent no. 5,788,121) in view of Love (US patent no. 4,306,668). Sasaki discloses a flexible bag (104) disposed in a box with diagonal seams with hanger connections (14, figure 4) for receiving a hanger and disposed inwardly of the top perimeter edge of the bag. However, Sasaki does not disclose a hanger system of the elastic type attached to the box and the top of the bag at the hanger connections. Love discloses a hanger system for supporting a large volume flexible container in a box, the large volume flexible container defining a sterile barrier to an interior of the container having a top side having a top outer perimeter edge and sidewalls in supportive contact with sidewalls (14, 15) of the box, the system comprising a container hanger (16, 17, figure 5) of the elastic type connected to the box and to a portion of the top side of the flexible container spaced inward from the top outer perimeter edge (figure 5) and applying an upward force to the portion of the flexible container during filling (col. 4, lines 17-20) wherein the flexible container has a perimeter greater than the perimeter of the box in the unstretched condition of the box along the same plane such that the bag is supported by the wall of the box. It would have been obvious to one of ordinary skill in the art to have provide Sasaki's bag-in-box system with elastic hanger for suspending the bag during filling and to provide a bag perimeter greater than the box perimeter such that the bag wall is supported by the box walls as

taught to be desirable by Love. Further it would have been an obvious matter of design choice to have the hanger connection at 35%-65% of the length of the seam measured from the outer corner of the flexible container.

Claim 38 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

Response to Arguments

Applicant's arguments with respect to claims 12 and 18-48 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Dunn et al teach providing hole (117, figure 3) in seam for hanger. LaFleur et al, Tisi, Krein, Poulton, Taylor, Oswalt et al, Wilcox, Kupersmit, Love, Deringer, Croley, Zublin, and Khanna et al demonstrate flexible container in a box or box-like apparatus.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Korie H. Chan whose telephone number is 703-305-8079. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leslie Braun can be reached on 703-308-2156. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Korie H. Chan
Primary Examiner
Art Unit 3632

khc
June 22, 2004